



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0915]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0636. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (OMB Control Number 0910-0636)-

-Extension

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States.

FDA is requesting public comment on estimates of annual submissions from these respondents, as required by Public Law 109-462 and described in the guidance. This guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including follow-up reports under 760(c)(2) of the FD&C Act, and how to submit these reports. The estimates for annual reporting burden and recordkeeping are based on FDA's knowledge of adverse drug experience reports historically submitted per year for prescription drug products and for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports and to maintain records.

FDA receives approximately 2,500 serious adverse event reports for nonprescription drug products marketed under approved applications, which comprise approximately 20 percent of the overall nonprescription drug market. Based on this experience, we estimate between 10,000 and 15,000 (i.e., 12,500) total annual responses for nonprescription drugs marketed without an approved application.

In the Federal Register of December 27, 2011 (76 FR 80946), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments on the information collection.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reports of Serious Adverse Drug Events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	2	25,000
Total					25,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance recommends that responsible persons maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports. Although the guidance does not provide recommendations on recordkeeping activities generally under section 760(e) of the FD&C Act, FDA is providing an estimate for the burden of this collection. Historically, serious adverse event reports comprise approximately two-thirds and nonserious adverse event reports comprise approximately one-third of the total number of postmarketing adverse event reports associated with drugs and biologic therapeutics (except

vaccines) received by FDA. Based on this generalization, FDA estimates the total annual records to be approximately 20,000 records per year. FDA estimates that it takes 5 hours to maintain each record and the recordkeeping burden as follows:

Table 2.--Estimated Annual Recordkeeping Burden¹

	No of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000
Total					100,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.